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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID FIKSTAD and DANYI QUAN

Appeal 2010-001150
Application 09/871,318
Technology Center 1600

Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a device for transdermal delivery of lasofoxifene. Claims 14, 18, 19, and 25-27, the

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

only claims on appeal, stand rejected for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

This application was the subject of appeal 2008-3445, decided Aug. 28, 2008. In that appeal, we affirmed the rejection of claims 3-5, 17, 22-24, and 28-40 on the basis of obviousness (2008-3455 Decision, pages 5-8 and 9-10), but reversed the rejection of claims 14, 18, 19, and 25-27 (*id.* at 9). We entered a new rejection of claims 14, 18, 19, and 25-27 under 35 U.S.C. § 103(a) (*id.* at 10-11). Appellants resumed prosecution before the Examiner and submitted a declaration under 37 C.F.R. § 1.132 to address the new rejection. The Examiner maintained the rejection and this appeal followed.

Claims 14, 18, 19, and 25-27 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 14 is representative and reads as follows:

> 14. A device for administering an active agent to the skin or mucosa of an individual comprising a laminated composite of:
>
> a. a backing layer defining an upper portion of a reservoir and extending to the periphery of a peel seal disk;
>
> b. an active agent-permeable membrane extending to the periphery of the peel seal disk and the backing layer, and underlying the backing layer, the backing layer and membrane defining;
>
> c. the reservoir therebetween that contains a transdermal formulation comprising an effective amount of lasofoxifene or a pharmaceutically acceptable salt thereof;
>
> d. the peel seal disc underlying an active agent-permeable membrane;
>
> e. a heat seal about the periphery of the peel seal disc, the active agent-permeable membrane and the backing layer;

f. an adhesive overlay having a central portion overlying the backing layer and a peripheral portion that extends beyond the periphery of the peel seal disc; and

g. a removable release liner underlying the peripheral portion of the adhesive overlay and the peel seal disc.

Issue

Claims 14, 18, 19, and 25-27 stand rejected under 35 U.S.C. § 103(a) based on Ebert,[2] Cormier,[3] and Ke[4] (Answer 3-4). The Examiner finds that Ebert discloses a transdermal delivery device having the structure recited in the claims but does not teach the inclusion of lasofoxifene (*id.* at 4). The Examiner finds that Cormier discloses a transdermal device that "delivers various active agents including antiestrogen and antiosteoporotic agents such as tamoxifen and raloxifene" although not lasofoxifene (*id.*) and that Ke discloses transdermal administration of lasofoxifene, as well as raloxifene and tamoxifen (*id.* at 4-5). The Examiner concludes that it would have been obvious to combine Ebert's device with the transdermal administration of lasofoxifene taught by Cormier and Ke since Ebert teaches that its device is useful for administering a variety of agents including estradiol (*id.* at 5).

Appellants contend that Ke only discloses topical administration of a lasofoxifene solution, not administration using a transdermal delivery device (Appeal Br. 11) and that, as evidenced by the Coop Declaration, the differences in lasofoxifene's structure and properties, as compared to estradiol, tamoxifen, and raloxifene, support the nonobviousness of the claimed device (Appeal Br. 13-14).

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[2] Ebert et al., US 5,662,925, Sept. 2, 1997.
[3] Cormier et al., US 6,203,817 B1, Mar. 20, 2001.
[4] Ke et al., US 6,323,232 B1, Nov. 27, 2001.

The issue presented is: Does a preponderance of the evidence of record support the Examiner's conclusion that combining the disclosures of the cited references represents a predictable use of prior art elements according to their established functions?

Findings of Fact

1. We adopt the fact-finding set out in the 2008-3455 opinion (pages 5, 10-11) and in the Answer (pages 4-5).

2. Appellants have submitted a declaration under 37 C.F.R. § 1.132 of Andrew Coop (filed Oct. 27, 2008).

3. Dr. Coop declared that lasofoxifene has a different ring structure than tamoxifen, droloxifene, idoxifene, raloxifene HCl and tamoxifen citrate, and that its ring structure "will lead to significantly different physical properties compared to all other compounds listed" (Coop Declaration, ¶ 9).

4. Dr. Coop declared that these compounds "all also possess differing functional groups from each other. . . . These functional groups affect properties such as the stability of the active ingredient" and other properties relevant to transdermal administration from a matrix (*id.* at ¶ 10).

5. Dr. Coop declared that "each of these differences in chemical make up of these compounds introduces a layer of unpredictability to the use of these compounds, especially with regard to formulations" (*id.* at ¶ 11).

6. Dr. Coop declared that "there is also unpredictability in the transdermal device in itself" because each of the compounds listed in the cited references has different properties that "would require modifications of the device" to account for those properties, "[a]ll of which are unpredictable

factors that may or may not lend a drug to being formulated for transdermal delivery" (*id.* at ¶ 12).

7. Dr. Coop concluded that he "believe[s] that one who is skilled in the field, would not recognize that the topical administration of an aqueous solution of lasofoxifene as described in Ke et al. would in any way predictably dictate that the same concept would translate to the transdermal delivery of lasofoxifene using the device and methods" now claimed (*id.* at ¶ 13).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

"[A] presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). After a rejection is made based on the presumptively enabled disclosure of a prior art patent, the applicant "can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." *Id.*

Analysis

We and the Examiner have found that Ebert discloses a transdermal drug delivery device that meets the structure recited in claim 14, absent the lasofoxifene (2008-3455 opinion, pages 10-11; Answer, page 4). Ebert discloses that its device is suitable for administering a variety of active agents (Ebert, col. 4, ll. 4-38), including estradiol (*id.* at col. 4, l. 20). Ke

discloses treating osteoporosis with an estrogen agonist/antagonist combined with a prostaglandin (Ke, col. 3, ll. 43-47), including a combination of lasofoxifene and prostaglandin PGE2 (*id.* at col. 40, ll. 48-55). Ke also discloses that "the compounds of this invention can be administered individually or together in any conventional oral, parenteral or transdermal dosage form" (*id.* at col. 37, ll. 14-16) and that "[f]or purposes of transdermal (e.g., topical) administration" aqueous solutions similar to those used for parenteral administration are appropriate (*id.* at col. 37, ll. 49-52).

We adhere to our previous conclusion that, in view of these disclosures, a person of ordinary skill in the art would have considered it obvious to administer lasofoxifene using Ebert's transdermal drug delivery device, because Ebert discloses that its device is suitable for administering a variety of drugs and Ke expressly suggests transdermal delivery of a composition comprising lasofoxifene.

Appellants argue that Ke "only discloses a liquid solution for topical administration" (Appeal Br. 11), which "is markedly different from the transdermal drug delivery system claimed" (*id.*). *See also* Reply Br. 5 (Ke "at most implies that a solution, such as a parenteral solution, may be applied topically").

This argument is not persuasive. In addition to disclosing that topical administration is an example of a transdermal route of administration (Ke, col. 37, ll. 49-52), Ke expressly states that its compounds – including lasofoxifene (*id.* at col. 40, l. 49) – "can be administered individually or together in any conventional . . . transdermal dosage form" (*id.* at col. 37,

ll. 14-16). Ke's disclosure of transdermal delivery is not limited to applying a solution topically.

Appellants also argue that "[f]or claims that involve chemical compounds, a proper obviousness analysis first requires the Examiner to consider similarities in chemical structure" (Appeal Br. 14). Appellants argue that, as evidenced by the Coop Declaration, the structure of lasofoxifene is very different from estradiol and the compounds described in Cormier and "these differences must be taken into account when formulating transdermal delivery devices since they introduce unpredictability" (*id.* at 15), which the Examiner did not adequately address (*id.* at 16).

Dr. Coop's testimony, however, does not support Appellants' position that delivering Ke's lasofoxifene using Ebert's device would not have been obvious. Dr. Coop points out that lasofoxifene's structure and properties differ from those of other compounds, and that these differences would need to be taken into account when designing a system for transdermal delivery of lasofoxifene. Dr. Coop does not, however, provide any reasoned basis for concluding that modifying Ebert's transdermal drug delivery device to administer lasofoxifene would have required anything more than routine experimentation.

Ebert lists numerous types of drugs that can be used in its device, and groups them according to their effects, not their structures. *See* Ebert, col. 4, ll. 4-14 ("antiinflammatory drugs, analgesics, antiarthritic drugs," etc.). Ebert also suggests numerous specific drugs, which differ structurally from each other, for use in its device. *See id.* at col. 4, ll. 19-38 ("steroids . . . , nitro-compounds . . . , oxicam derivatives . . . , sulfated polysaccharides").

Similarly, Cormier discloses that a wide variety of drugs are suitable for transdermal administration in its method. (*See* Cormier, col. 7, ll. 24-67.) These disclosures provide evidence that people working in this field routinely modified transdermal drug delivery systems to administer different drugs, with different structures and chemical properties.

In addition, Ke expressly states that lasofoxifene can be administered in any conventional transdermal dosage form. (Ke, col. 37, ll. 14-16; col. 40, ll. 49-51.)

Ebert's disclosure that numerous drugs can be delivered using its transdermal delivery device, and Ke's disclosure that lasofoxifene can be administered using any conventional transdermal dosage form, are presumed to be enabled by the disclosures of Ebert and Ke. *Amgen*, 314 F.3d at 1355. The only evidence that Appellants have provided to rebut that presumption is the Coop Declaration, which does not provide an adequate factual basis on which to conclude that undue, rather than routine, experimentation would have been required to administer lasofoxifene transdermally. *See In re Beattie*, 974 F.2d 1309, 1313 (Fed. Cir. 1992) (opinion evidence in declarations has little value without factual support).

Conclusion of Law

A preponderance of the evidence of record supports the Examiner's conclusion that combining the disclosures of the cited references represents a predictable use of prior art elements according to their established functions.

SUMMARY

We affirm the rejection of claims 14, 18, 19, and 25-27 under 35 U.S.C. § 103(a) based on Ebert, Cormier, and Ke.

In the previous appeal of this application, we also affirmed the rejection of claims 3-5, 17, 22-24, and 28-40 under 35 U.S.C. § 103(a) based on Cormier and Ke.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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